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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,147	01/29/2004	Andries Jan Smit	VOB-34537US1	4624

86378 7590 06/09/2010

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EXAMINER	
BERHANU, ETSUB D	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
06/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/767,147	SMIT ET AL.	
	Examiner	Art Unit	
	ETSUB D. BERHANU	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,34-40,43-45,47-58,60-62 and 64-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49,50 and 69-72* is/are allowed.

6)☒ Claim(s) *32,34,35,38-40,43-45,47,48,54-58,60-62,64-68,73 and 74* is/are rejected.

7)☒ Claim(s) *36,37 and 51-53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/10*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2010 has been entered.

Claim Objections

2. Claim 73 is objected to because of the following informalities: there are two Claim 73s. The second Claim 73 has been renumbered as Claim 74 for the purposes of this Office Action. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 34, 35, 62, 64, 66-68, 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 62 and 66, the Specification of the current invention fails to provide details of a method or apparatus wherein measured fluorescent radiation emitted in response to irradiation is received from

only a portion of an irradiation portion of a skin surface. The Specification discloses that radiation from multiple different portions of the skin surface are detected by a detector (page 8, lines 4-8) and that the detector detects the total amount of light coming from the irradiated skin (page 11, lines 6-7). Furthermore, Figure 1 shows receiving light from an entire portion of an irradiated skin surface. Regarding claims 67 and 68, the Specification fails to disclose that a size of the portion of the irradiated skin surface portion from which a measured fluorescent radiation is received is at $1cm^2$.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 32, 38-40, 43-45, 47, 48, 54-58, 60, 61 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kollias et al.'059 (USPN 6,505,059) further in view of Anderson et al.'127 (USPN 6,436,127).

Kollias et al.'059 discloses an instrument and method for measuring glucose concentrations by using fluorescence (see ABSTRACT). Figure 2 of Kollias et al.'059 discloses a light source 14 and a detector 18. Kollias et al.'059 discloses: an illumination area of about $1cm^2$ or less (col. 5, lines 57-58); use of wavelengths in the range of 300-345 nm (col. 5, lines 27-32); a measuring window of detector 18 is held away from the surface of the skin since contact with the skin is made using a probe comprising optical fibers (see Figure 10A and col. 6, lines 51-53); an excitation wavelength of 420nm and an emission wavelength of 500 nm (col. 6, lines 46-67); reflected radiation being detected (see Figures 10A and 10B); multiple wavelengths in a normalizing section for determining glucose (col. 10, line 59 – col. 11, line 12), wherein normalizing one wavelength by using another wavelength is considered to be

aggregating detected fractions of fluorescent radiation to an aggregated amount of detected electromagnetic radiation; ends of optical fibers (Figures 10A and 10B), wherein the ends include an irradiation and measuring window, and wherein the ends move relative to a measuring window of the detector which is located in the analyzing instrument, when the fiber is placed on the skin, the fiber and windows capable of being placed at an angle of 25-65 degrees relative to the skin surface; filters, lamps and laser diodes as light sources (col. 6, lines 25-28, col. 14, lines 1-10, col. 9, line 65 – col. 10, line 3); irradiation being changed when measuring a reflected and emission radiation (col. 13, line 66 – col. 14, line 47); an irradiation being performed in a pulse fashion (col. 9, line 6 – col. 10, line 12); different wavelengths being chosen using a wavelength selector (Figure 11, element 107 and col. 13, line 66 – col. 14, line 47); a support structure (col. 7, line 65 – col. 8, line 20) and control means (Figure 2, element 12) for controlling the excitation radiation of a light source, wherein the control means allows the apparatus to be capable of intermittently irradiating skin tissue and for separately detecting radiation from the skin tissue.

Kollias et al.'059 discloses all the elements of the current invention, as discussed above, except for the measured fluorescent radiation being received from a portion of the irradiated surface portion of the skin, wherein the size of the skin surface from which the measured fluorescent radiation is received is at least $1cm^2$. Kollias et al.'059 fails to disclose the size of the fiber optic cable that receives the measured fluorescent radiation, however, Kollias et al.'059 does disclose that the fiber optic cable that delivers radiation to the skin is of a size to irradiate a skin surface of about $1cm^2$ or less. It would have been within the skill of the art to use the same sized fiber optic cable to receive the measured fluorescent radiation as the fiber optic cable used to deliver the radiation, since Kollias et al.'059 fails to disclose the size of the return fiber optic cable and Kollias et al.'059 teaches the use of a fiber optic cable (the radiation delivery fiber optic cable) capable of being used as the return fiber optic cable. Anderson et al.'127 teaches that fiber optic bundles comprising separate radiation and delivery fibers are an alternate

equivalent to a fiber optic bundle comprising a single fiber wherein the single fiber both delivers and receives diagnostic radiation data to and from the skin of a patient (col. 17, lines 55-67). It would have been within the skill of the art to substitute a fiber optic bundle comprising a single optic fiber to both deliver radiation and receive radiation from the same skin site, as taught by Anderson et al.'127, for the multiple fiber probe of Kollias et al.'059, since it has generally been held within the skill of the art to substitute alternate equivalent expedients.

Response to Arguments

7. Applicant's arguments, see pages 12-13 of the Remarks, filed 22 April 2010, with respect to the rejection of claims 34, 35, 62-68, 73 and 74 in view of Kollias et al. in view of Anderson et al. have been fully considered and are persuasive. The rejection of these claims in view of Kollias et al. in view of Anderson et al. has been withdrawn. However, as discussed in paragraph 4 above, a new ground of rejection has been made regarding claims 34, 35, 62, 64, 66-68, 73 and 74. Applicant's arguments on pages 14-17 of the Remarks with respect to the rejection of claims 32, 34-40, 43-45, 47, 48, 54-57, 60 and 61 have been fully considered and are persuasive. However, a new ground of rejection has been made with Kollias et al. further in view of Anderson et al. as discussed in paragraph 6 above. Applicant argues on page 15 of the Remarks that using the same fibers for irradiating a skin surface and picking up radiation from the skin surface would require a two-way coupler, and as such, would complicate the design, attenuate light and constitute a likely source of noise and other artefacts in the method and apparatus of Kollias et al. Examiner respectfully disagrees. Anderson et al. provides sufficient disclosure to modify the dual optical fiber configuration of Kollias et al. into a single optical fiber, stating that individual optical fibers in a medical apparatus configured to separately irradiate and detect light are capable of being replaced by a single optical fiber in the medical apparatus configured to both irradiate light and detect light. Anderson et al. does not indicate that a separate two-way coupler is required in

order to implement the single optical fiber. As it has generally been held within the skill of the art to substitute alternate equivalent expedients, Applicant's argument is not persuasive. Applicant further argues on pages 16-17 of the Remarks that a range of "less than about 1 square cm" does not unambiguously include the value 1square cm. Examiner respectfully disagrees. "Less than about 1 square cm" includes 1 square cm as the term "about" comprises values just above and below 1 square cm. The fact that Kollias et al. discloses that 0.2 square centimeters is a preferred value does not take away from the fact that Kollias et al. discloses a value of "about 1 square cm". The disclosed range of Kollias et al. does not end short of 1square cm; it ends at about 1 square cm, which, as discussed above, includes values just above 1 square cm and also includes 1 square cm. For these reasons, Applicant's arguments are not persuasive.

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, a method for determining an advanced glycation/glycosylation end product content of non-locally anomalous, intact skin tissue of a human individual wherein the method comprises simultaneously receiving measured fluorescent radiation from only a portion of an irradiated portion of a skin surface, in combination with the other claimed steps. None of the prior art teaches or suggests, either alone or in combination, an apparatus comprising a detector that simultaneously receives fluorescent radiation from only a portion of an irradiated skin surface portion, in combination with the other claimed elements. None of the prior art teaches or suggests, either alone or in combination, a method for determining an advanced glycation/glycosylation end product content of non-locally anomalous, intact skin tissue of a human individual wherein the method comprises receiving fluorescent radiation via a measuring window oriented at an angle of 25-65 degrees relative to an irradiation portion of the surface of the skin, in combination with the other claimed

elements. None of the prior art teaches or suggests, either alone or in combination, a method for determining an advanced glycation/glycosylation end product content of non-locally anomalous, intact skin tissue of a human individual wherein irradiated skin tissue is located behind an opening in a supporting structure held against the skin of the individual, in combination with the other claimed steps. None of the prior art teaches or suggests, either alone or in combination, an apparatus for determining an advanced glycation/glycosylation end product content of non-locally anomalous, intact skin tissue of a human individual wherein the apparatus comprises a measuring window bounding a surface area for passing fluorescent radiation to be detected from an irradiated portion of a skin surface, where the portion of the skin surface from which the amount of fluorescent radiation is received is larger than the surface area bound by the measuring window, in combination with the other claimed elements. None of the prior art teaches or suggests, either alone or in combination, an apparatus for determining an advanced glycation/glycosylation end product of content of non-locally anomalous, intact skin tissue of a human individual wherein the apparatus comprises a supporting structure, the supporting structure further supporting a measuring window oriented at an angle of 25-65 degrees relative to a plane in which a surface portion of skin tissue to be irradiated is to be located, in combination with the other claimed elements. None of the prior art teaches or suggests, either alone or in combination, a method for determining an advanced glycation/glycosylation end product content of non-locally anomalous, intact skin tissue of a human individual wherein the method comprises irradiating skin tissue with electromagnetic radiation via an opening in a surface contacting the skin, in combination with the other claimed steps.

9. Claims 36, 37 and 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 49, 50 and 69-72 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

/Etsub D Berhanu/
Examiner, Art Unit 3768